



NDA 19-516/S-016

The Purdue Frederick Company
One Stamford Forum
Stamford, CT 06901-3431

Attention: Michael G. Harlow
Associate Director, U.S. Regulatory Affairs

Dear Mr. Harlow:

Please refer to your supplemental new drug application dated July 25, 2001, received July 26, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MS Contin (morphine sulfate controlled-release) Tablets.

We acknowledge receipt of your submission dated September 24, 2001.

This "Changes Being Effected" supplemental new drug application provides for changes to the WARNINGS, ADVERSE REACTIONS, and OVERDOSAGE sections of the label.

We have completed the review of this supplemental application, as amended, and it is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Lisa Basham, Regulatory Project Manager, at (301) 872-7441.

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

Cynthia McCormick
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